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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/783,127

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EXAMINER

BEISNER, WILLIAM H

ART UNIT

PAPER NUMBER

1797

MAIL DATE

DELIVERY MODE

08/06/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/783,127	Applicant(s) OH ET AL.	
	Examiner WILLIAM H. BEISNER	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 April 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) 3-5, 7-14 and 16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 6 and 15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I, Species i), in the reply filed on 6/27/2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
2. Claims 3-5, 7-14 and 16 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention and/or species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 6/27/2007. Note, Applicants did not state which claims encompass the elected species. As a result, it is determined that claims 6 and 15 correspond to elected species i) while claims 1 and 2 are generic. Therefore, claims 1, 2, 6 and 15 will be examined on their merits.

Priority

3. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

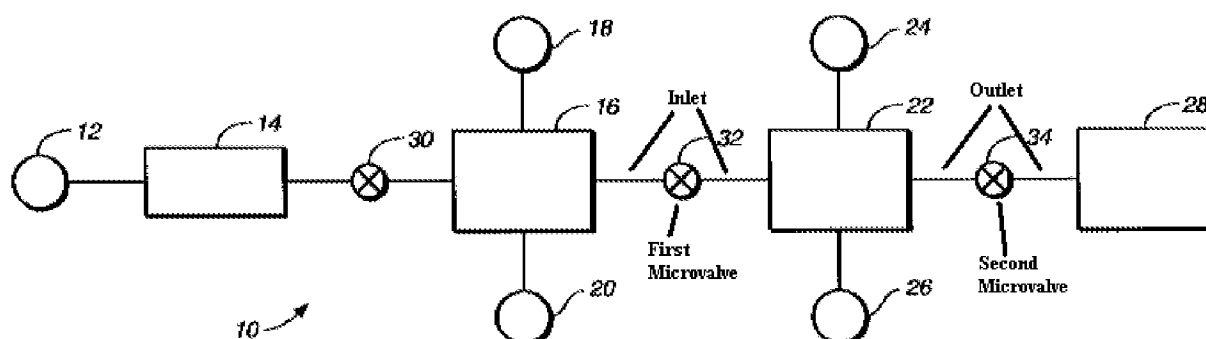
5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1, 2, 6 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Blackburn (US 6,875,619) in view of Robotti et al.(US 2002/0054835).

The reference of Blackburn discloses a PCR device (See Figure 8 reproduced hereafter) that includes an inlet ; an outlet; a PCR channel (22); a first microvalve (32); and a second microvalve (34).

**FIG. 8**

Claim 1 differs by reciting that the device includes a sol-gel transformable material, which transforms from a sol state into a gel state at a temperature lower than DNA denaturation temperature, annealing temperature and extension temperature and higher than room temperature.

The reference of Robotti et al. discloses that it is known in the art of microfluidic devices to employ thermoreversible polymeric gels as microvalves (See paragraphs [0032]-[0033]). The reference lists methyl cellulose as a known gel material.

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to employ thermoreversible gels in the system of the primary reference for the known and expected result of providing an alternative means recognized in the art to achieve the same result, control of the flow of fluids within a microfluidic device, and for the advantages discussed by the reference of Robotti et al. (See paragraph [0071]).

With respect to the temperature requirement of the gel of claim 1, the reference of Robotti et al. discloses the use of methyl cellulose which is disclosed in the instant specification as a material that meets this claim limitation (See instant claim 2).

With respect to claim 2, the reference of Robotti et al. discloses the use of methyl cellulose (See paragraph [0033]).

With respect to claims 6 and 15, the reference of Robotti et al. discloses that the valve structure can include intersecting flow paths wherein one of the flow paths is filled with the reversible material (See paragraph [0037]).

Response to Arguments

8. With respect to the rejection of Claims 1, 2, 6 and 15 under 35 U.S.C. 103(a) as being unpatentable over Blackburn (US 6,875,619) in view of Robotti et al.(US 2002/0054835), Applicants argue that the rejection is improper for the following reasons:

i) *Blackburn teaches that hydrogels and gel pads can be used to bind the biological materials* (See page 6, paragraph 1, of the response dated 4/18/2008).

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In this case, the reference of Blackburn discloses a PCR channel with valves on either side. While the valves are not made of a thermally reversible gel, the reference of Robotti has been cited to evidence that it would have been within the purview of one of ordinary skill in the art to employ a microvalve made of a

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thermally reversible gel. It is further noted that the gel referred to by Applicants has nothing to do with the microvalves (32,34) and/or PCR channel (22) disclosed by the reference of Blackburn. The gel is employed in an assay or detection chamber (28) of the device which is a separate element with respect to the microvalves (32,34) and PCR channel (22).

ii) Robotti teaches a thermoreversible gel valve but does not teach that a channel positioned between the valves can be used for polymerase chain reaction and does not teach a material that transforms from a sol state into a gel state at the temperatures required of the instant claims (See page 6, paragraph 2, of the response dated 4/18/2008).

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In this case, the reference of Robotti was relied upon as a teaching reference that evidences that it is within the purview of one having ordinary skill in the art to employ a thermally reversible gel as a microvalve (18) in a microfluidic device. The reference even further evidences that the thermally reversible gel valves (18) can be used to isolate a microchannel or microchamber (17). With respect to the transformation temperatures, while the reference does not specifically state the transformation temperatures in terms of PCR reactions, the reference discloses the use of methyl cellulose (See paragraph [0033]) which would inherently meet the claimed properties of the gel required of claim 1.

iii) *One of ordinary skill would not be motivated to employ the thermoreversible gels of Robotti in the device of Blackburn because the device of Blackburn required permanently cross-linked hydrogels which are used for binding materials introduced into the channel of the device* (See page 6, paragraphs 3-4, of the response dated 4/18/2008).

In response, Applicants' comments are not to be persuasive because the gel referred to by Applicants has nothing to do with the microvalves (32,34) and/or PCR channel (22) disclosed by the reference of Blackburn. The gel is employed in an assay or detection chamber (28) of the device which is a separate element with respect to the microvalves (32,34) and PCR channel (22). The fact that the gel of the reference of Blackburn is used in a different manner would not have dissuaded one of ordinary skill in the art for the reasons previously discussed above.

iv) *Blackburn does not teach microvalves as contended by the Examiner. Applicants stress that Blackburn discloses the use of microfluidic pumps or capillary stop valves and concludes that one of ordinary skill in the art would be dissuaded from replacing it with a thermally reversible gel* (See pages 6-7 of the response filed 4/18/2008).

In response, Applicants' comments are found to be persuasive because while the preferred microvalves of Blackburn are microfluidic pumps or capillary stop valves, the reference clearly states that "A variety of valves are known in the art" (See column 48, lines 47-48). One of ordinary skill in the art would have recognized that any of the known microfluidic valves could have been used in the system and, as evidenced by the reference of Robotti, one of ordinary skill would have recognized that a thermally reversible gel could have been used for the advantages disclosed by the reference of Robotti.

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to WILLIAM H. BEISNER whose telephone number is (571)272-1269. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:15am to 3:45pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

**/William H. Beisner/
Primary Examiner
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WHB